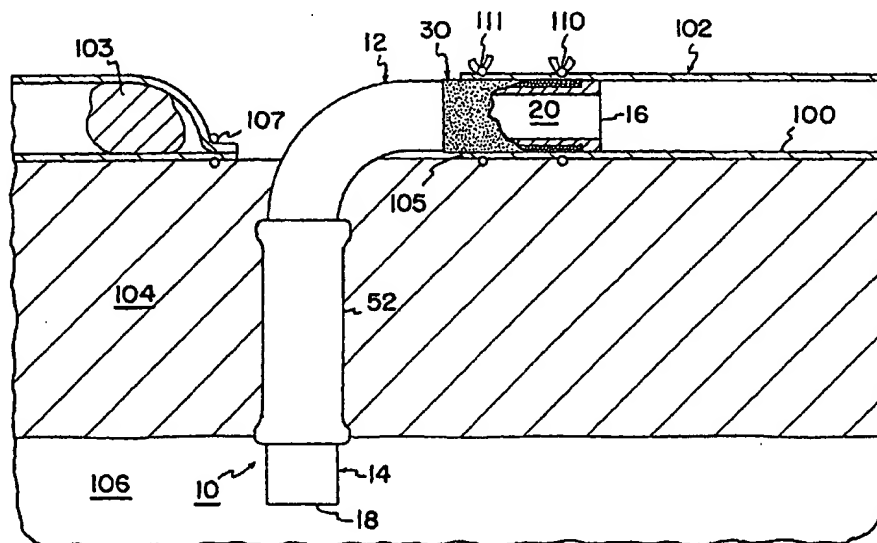




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<p>(51) International Patent Classification ⁷ : A61B 17/11, 17/72, A61F 2/00, 2/06</p>	<p>A1</p>	<p>(11) International Publication Number: WO 00/45711 (43) International Publication Date: 10 August 2000 (10.08.00)</p>
<p>(21) International Application Number: PCT/US99/26552 (22) International Filing Date: 10 November 1999 (10.11.99) (30) Priority Data: 09/246,596 8 February 1999 (08.02.99) US (71) Applicant: HEARTSTENT CORPORATION [US/US]; 651 Campus Drive, Saint Paul, MN 55112 (US). (72) Inventors: TWEDEN, Katherine, S.; 1175 Ashley Lane, Mahtomedi, MN 55115 (US). VANNEY, Guy, P.; 7489 Meadowood Court, Brooklyn Park, MN 55444 (US). ODLAND, Thomas, L.; 6367 Deerwood Lane, Lino Lakes, MN 55014 (US). (74) Agent: BRUESS, Steven, C.; Merchant & Gould P.C., 3100 Norwest Center, 90 South Seventh Street, Minneapolis, MN 55402-4131 (US).</p>		<p>(81) Designated States: AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), DM, EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (Utility model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>

(54) Title: TRANSMYOCARDIAL IMPLANT WITH CORONARY INGROWTH



(57) Abstract

The transmural implant for establishing blood flow through the myocardium between a heart chamber and a lumen of a coronary vessel includes a hollow rigid conduit (10) extending between the lumen and the heart chamber. The conduit includes a first portion (12) for placement in the vessel. The first portion includes an attachment location spaced from an open end for securing a suture around the vessel overlying the first portion at the attachment location. The conduit is formed of a rigid material to resist deformation in response to contraction of the myocardium and the conduit is resistant to thrombus. A tissue growth-inducing material (52) is secured to an exterior of the first portion at the attachment location.

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TRANSMYOCARDIAL IMPLANT WITH CORONARY INGROWTH**BACKGROUND OF THE INVENTION****1. Field of the Invention**

5 This invention pertains to an implant for directing blood flow directly between a chamber of the heart and a coronary vessel. More particularly, this invention pertains to such an implant with an enhanced design for fixating the implant in a coronary vessel.

2. Description of the Prior Art

10 U.S. Pat. No. 5,755,682 dated May 26, 1998 and PCT Application No. PCT/US97/13980 (International Publication No. WO 98/06356 based on U.S. Patent Application Serial No. 08/882,397 filed June 25, 1997) teach an implant for defining a blood flow conduit directly from a chamber of the heart to a lumen of a coronary vessel. An embodiment disclosed in the aforementioned patent and applications
15 teaches an L-shaped implant in the form of a rigid conduit. The conduit has one leg sized to be received within a lumen of a coronary artery and a second leg sized to pass through the myocardium and extend into the left ventricle of the heart. As disclosed in the above-referenced patent and applications, the conduit is rigid and remains open for blood flow to pass through the conduit during both systole and
20 diastole. The conduit penetrates into the left ventricle in order to prevent tissue growth and occlusions over an opening of the conduit.

Commonly assigned and co-pending U.S. patent application Serial No. 08/944,313 filed October 6, 1997, entitled "Transmyocardial Implant" teaches an implant such as that shown in the aforementioned '682 patent with an enhanced
25 fixation structure. The enhanced fixation structure includes a fabric surrounding at least a portion of the conduit to facilitate tissue growth on the exterior of the implant.

Implants such as those shown in the aforementioned applications include a portion to be placed within a coronary vessel and a portion to be placed within the myocardium. When placing a portion of the implant in the coronary vessel, the
30 vessel is axially incised a length sufficient to insert the implant. The implant vessel portion is placed within the vessel.

In a preferred embodiment, the implant is rigid. An artery is flexible. A pulsing and alternating flow of blood through the rigid implant and flexible vessel can result in relative movement between through the implant and vessel. As a result
35 of such movement, a rubbing action may occur with the implant causing cellular and

extra-cellular matrix ("ECM") damage to the vessel. Such damage may stimulate cellular migration and proliferation and ECM changes resulting in a fibrotic and thrombotic response which grows to block the implant or artery. Also, as the artery enlarges due to blood flow, an annular gap may exist around the implant in which
5 stagnant blood may collect and stimulate thrombosis. Also, a smooth titanium implant may slip axially relative to a vessel in which the implant is placed. It is an object of the present invention to provide an implant with a reduced likelihood of such response.

SUMMARY OF THE INVENTION

10 According to a preferred embodiment of the present invention, a transmyocardial implant is disclosed for establishing blood flow through the myocardium between a heart chamber and a lumen of a coronary vessel. The implant includes a hollow rigid conduit extending between the lumen and the heart
15 chamber. The conduit includes a first portion for placement in the vessel. The first portion includes an attachment location spaced from an open end for securing a suture around the vessel overlying the first portion at the attachment location. The conduit is formed of a rigid material to resist deformation in response to contraction of the myocardium and the conduit is resistant to thrombus. A tissue growth-
20 inducing material is secured to an exterior of the first portion at the attachment location.

BRIEF DESCRIPTION OF THE DRAWINGS

25 FIG. 1 is a side elevation view of a transmyocardial implant with a vessel ingrowth area, shown partially in section, according to the present invention with the implant in place in a heart wall and in a coronary vessel;

Fig. 2 is a cross-sectional view of a vessel portion of the implant of Fig. 1 with the vessel ingrowth area formed by a sintered metal layer according to one
30 embodiment of the present invention;

Fig. 3 is the view of Fig. 2 with the vessel ingrowth area formed a fabric layer according to an alternative embodiment of the present invention; and

Fig. 4 shows the view of Fig. 3 placed in a vessel and illustrating an attachment location.

DESCRIPTION OF THE PREFERRED EMBODIMENT

With initial reference to FIG. 1, a conduit 10 is shown in the form of an L-shaped rigid tube. The conduit 10 may be formed of titanium or other rigid biocompatible material such as nickel-titanium alloy or pyrolytic carbon or may be titanium or other material that is coated with pyrolytic carbon. The material of the conduit 10 is preferably a rigid material in order to withstand contraction forces of the myocardium, as will be described. In the preferred embodiment, the tube will have an outside diameter D_O of about 2 – 3 millimeters and an internal diameter D_I of about 1 – 2 millimeters to provide a wall thickness of about .5 millimeters.

The tube 10 has a first portion 12 sized to be received within the lumen of a coronary vasculature such as the lumen 100 of a coronary artery 102. The conduit 10 has a second portion 14 extending at a right angle to the axis of portion 12. The second portion 14 is sized to extend from the coronary artery 102 directly through a myocardium 104 and protrude into the left ventricle 106 of a patient's heart. The second portion 14 is sized to have a length sufficient for the portion 14 to protrude into the left ventricle 106. By way of example, such a length may be 25 mm.

The first portion 12 has a first opening 16 and the second portion 14 has a second opening 18 in communication with an interior 20 of the implant 10. Therefore, blood can freely flow through the implant 10 between the left ventricle 106 and the lumen 100 of the coronary artery 102.

As mentioned, the tube 10 is preferably formed of titanium or other smooth biocompatible material in order to resist tissue growth and thrombus deposition on the surfaces of the conduit 10. Titanium is a presently preferred material due its long-term use in the cardiovascular industry. Further, titanium is sufficiently rigid to withstand deformation forces caused by contraction of the myocardium 104 to avoid deformation of the tube 10 so that the tube 10 remains open during both diastole and systole.

Since the titanium is resistant to thrombus formation, the titanium of the tube 10 does not attach the device within the myocardium 104 and the lumen 100 of the patient. Therefore, the implant 10 includes a sleeve 52 of tissue growth-inducing material secured to an exterior surface of the conduit 10. In the embodiments of Fig. 1, the sleeve 52 resides exclusively on the second portion 14 in order to reside exclusively within the myocardium 104 after surgical placement of the implant 10.

Preferably, the sleeve 52 is formed of a fabric having biocompatible fibers defining interstitial spaces to receive tissue growth. An example of such a fabric is

polyethylene terephthalate (such as polyester fabric sold by DuPont Company under the trademark Dacron). Such a fabric permits rapid tissue integration into the fabric to anchor the fabric and, hence, the tube 10 to the patient's tissue. As a result, the sleeve 52 is selected to induce tissue attachment.

5 It is anticipated that tissue growth on and into the sleeve 52 could result in a buildup of tissue beyond the sleeve 52 to a thickness of about 1 millimeter. It is desirable that such tissue growth does not extend over end 18. Accordingly, the lower end of the sleeve 52 is spaced from end 18 by a distance greater than an anticipated thickness of tissue growth extension beyond the sleeve 52. Since the
10 anticipated thickness of tissue growth is about 1 millimeter, the lower end is preferably spaced 1 millimeter from tube end 18. However, a conservative additional spacing of 4–5 millimeters is preferred.

While a fabric tissue growth inducing material is illustrated, other materials could be used. For example, the tissue growth inducing material could be sintered
15 metal on the external surface of the tube 10. Sintered metal results in a porous surface to receive tissue growth. The area of the sintered metal will be spaced from end 18 to prevent tissue accumulation on the sintered area from growing over and blocking end 18.

It will be appreciated the description of a sleeve as described is the subject of
20 commonly assigned and copending U.S. patent application Ser. No. 08/944,313 filed October 6, 1997, entitled "Transmyocardial Implant", and filed in the name of inventors Katherine S. Tweden, Guy P. Vanney and Thomas L. Odland.

When placing the vessel portion 12 in the lumen 100, a length of the artery
102 distal to an obstruction 103 is dissected from the myocardium 104. An incision
25 105 is formed through the dissected artery 102. Sutures 107 ligate a proximal portion of the artery 102 distal to the obstruction 103. The vessel portion 12 is inserted through the incision 105 into the lumen 100 of a distal portion of the artery 102.

The vessel portion 12 is provided with a tissue ingrowth area 30 adjacent the
30 free end 16. The tissue ingrowth area 30 is spaced about 0.5 mm – 1.5 mm (preferably about 0.5 mm) from the free end 16 to avoid tissue growth from migrating into the interior 20 of the implant 10. While the tissue ingrowth area 30 could extend to the free end 16, it is presently anticipated that a short spacing of the area 30 from the free end 16 is desirable.

The tissue ingrowth area 30 is an annular surface surrounding the exterior of the vessel portion 12. The area 30 permits cellular (e.g., fibroblasts and extra-cellular matrix such as collagen) ingrowth from a vessel (e.g., artery or vein) surrounding the vessel portion 12. The area 30 is provided with a plurality of
5 exposed interstitial spaces to permit such ingrowth. The area 30 may be formed in any one of a number of ways to form such spaces. For example, in the embodiments of Figs. 1 and 2, the vessel portion 12 may be provided with a wide annular groove 13 terminating 0.5 mm from the free end 16. The groove 13 may be filled with
10 sintered metal 31 such as sintered titanium formed by elevating powder titanium to a sintering temperature. The resulting sintered area 30 is porous to permit ingrowth. In the embodiment of Fig. 2, the groove 13 may be filled with a polyester fabric wrap 31'. The fibers of the wrap 31' define the interstitial spaces.

The implant 10 is placed by inserting the vessel portion 12 into the lumen 100. A surgeon then places an attachment device 110, 111 around the vessel 102
15 and overlying the ingrowth area 30. For example, the attachment device 110, 111 may be a stay suture or clip. Preferably, a suture 110 is placed at an attachment location A near a distal end 32 of the ingrowth area 30. A second suture 111 is placed more proximally.

In use, tissue of the vessel 102 grows into the ingrowth area 30. Such growth
20 prevents relative movement between the vessel 102 and the implant 10. Further, such growth prevents a ballooning of the vessel 102 around the vessel portion 12 precluding the formation of stagnant blood areas between the vessel portion 12 and the vessel 102.

Having disclosed the present invention in a preferred embodiment, it will be
25 appreciated that modifications and equivalents may occur to one of ordinary skill in the art having the benefits of the teachings of the present invention. It is intended that such modifications shall be included within the scope of the claims are appended hereto.

WHAT IS CLAIMED:

1. A transmyocardial implant for establishing a blood flow path through a myocardium between a heart chamber and a lumen of a coronary
5 vasculature residing on an exterior of said wall, said implant comprising:
a hollow rigid conduit having a first portion and a second portion,
said first portion sized to be received within said lumen and said second
portion sized to extend from said vasculature through said myocardium
into said chamber, said conduit having open first and second ends on
10 respective ones of said first and second portions to define a blood flow
pathway within an interior of said conduit between said first and second
ends;
said conduit formed of a conduit material sufficiently rigid to resist
deformation and closure of said pathway in response to contraction of
15 said myocardium and said conduit material resistant to thrombus
formation;
a first tissue growth inducing material secured to an exterior of said
second portion for ingrowth of said myocardium into said first tissue
growth inducing material;
20 a second tissue growth inducing material secured to an exterior of
said first portion between said attachment location and said first open end
for ingrowth of said vessel into said second tissue growth inducing
material; and
said first portion including an attachment location spaced overlying
25 said second tissue growth inducing material for securing a suture around
a vessel overlying said first portion at said attachment location.
2. A transmyocardial implant according to claim 1 wherein said first and
second tissue growth inducing material is spaced from said first and
30 second ends a distance to avoid tissue growth on said tissue growth
inducing material from extending over and blocking said first and second
ends.

3. A transmyocardial implant according to claim 1 wherein said second tissue growth inducing material includes a plurality of fibers defining a plurality of interstitial spaces for receiving tissue growth and said tissue growth inducing material is biocompatible.
- 5
4. A transmyocardial implant according to claim 4 wherein said second tissue growth inducing material is a polyester fabric.
5. A transmyocardial implant according to claim 1 wherein said second tissue growth inducing material includes a porous layer on said exterior of said conduit.
- 10
6. A transmyocardial implant according to claim 1 wherein said porous layer is a sintered material.
- 15

FIG. 1

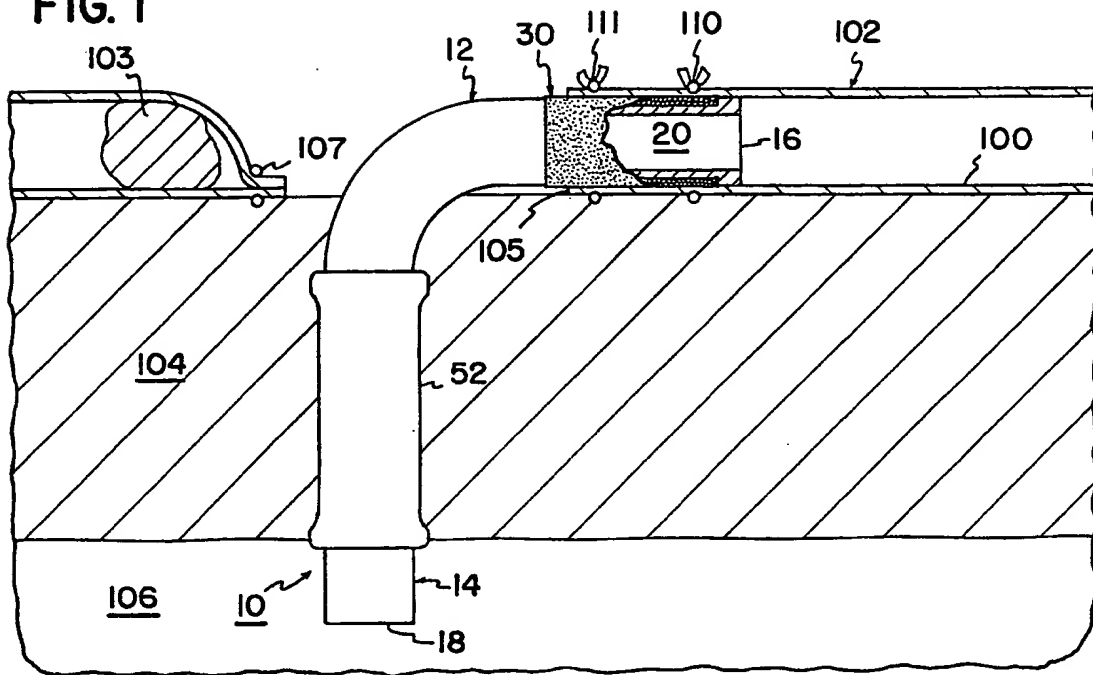


FIG. 2

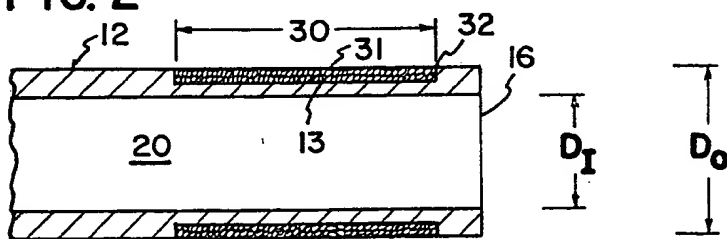


FIG. 3

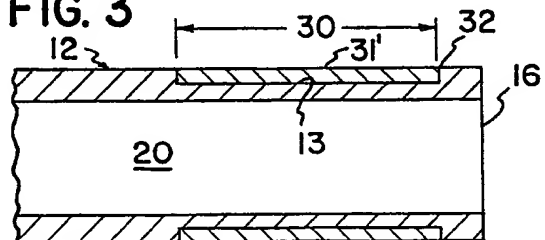
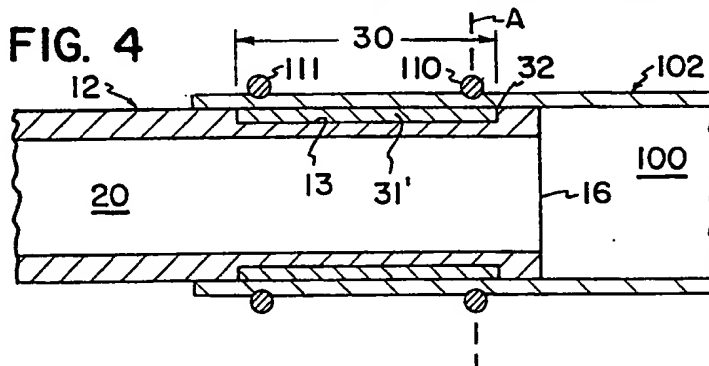


FIG. 4



INTERNATIONAL SEARCH REPORT

Inter. Appl. No.
PCT/US 99/26552

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/11 A61B17/72 A61F2/00 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 755 682 A (GIESE WILLIAM L ET AL) 26 May 1998 (1998-05-26) figures 1A, 3A column 9, line 46-67 column 13, line 3-23 column 13, line 54 -column 14, line 29 column 16, line 4-17	1
A	US 4 374 669 A (MAC GREGOR DAVID C) 22 February 1983 (1983-02-22) column 1, line 59-64 column 11, line 66 -column 13, line 26	1
A	WO 94 21197 A (BARD INC C R) 29 September 1994 (1994-09-29) page 5, paragraph 3; example 1	3,4
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☒ Further documents are listed in the continuation of box C.

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9 March 2000

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17/03/2000

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Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 545 227 A (KOVACS PAUL ET AL) 13 August 1996 (1996-08-13) figure 1 column 4, line 34-44	5,6

INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/US 99/26552

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5755682 A	26-05-1998	AU 4057397 A	06-03-1998
		DE 19735141 A	30-04-1998
		EP 0959815 A	01-12-1999
		GB 2316322 A,B	25-02-1998
		JP 2886847 B	26-04-1999
		JP 10146350 A	02-06-1998
		NO 990688 A	12-04-1999
		WO 9806356 A	19-02-1998
		US 5944019 A	31-08-1999
US 4374669 A	22-02-1983	CA 1069252 A	08-01-1980
		CA 1078552 A	03-06-1980
		DE 2620631 A	11-11-1976
		FR 2310122 A	03-12-1976
		JP 52001995 A	08-01-1977
		US 4280514 A	28-07-1981
		US 4355426 A	26-10-1982
		US 4459252 A	10-07-1984
		US 4458366 A	10-07-1984
		US 4627836 A	09-12-1986
		US 4101984 A	25-07-1978
		US 4934381 A	19-06-1990
		US 4281669 A	04-08-1981
		US 4936317 A	26-06-1990
		CA 1105652 A	28-07-1981
		CA 1068052 A	18-12-1979
		CA 1100191 A	28-04-1981
		CA 1115456 A	05-01-1982
WO 9421197 A	29-09-1994	US 5413598 A	09-05-1995
US 5545227 A	13-08-1996	US 5509933 A	23-04-1996
		US 5169597 A	08-12-1992
		AU 5219693 A	16-06-1994
		CA 2110779 A	08-06-1994
		EP 0601804 A	15-06-1994
		JP 6233811 A	23-08-1994
		US 5477864 A	26-12-1995
		US 5573401 A	12-11-1996
		US 5690670 A	25-11-1997
		US 5782910 A	21-07-1998
		US 5716400 A	10-02-1998
		US 5676632 A	14-10-1997
		US 5562730 A	08-10-1996
		US 5713947 A	03-02-1998
		US 5685306 A	11-11-1997
		US 5674280 A	07-10-1997
		US 5683442 A	04-11-1996
		AT 104865 T	15-05-1994
		AU 6827490 A	27-06-1991
		CA 2032875 A	22-06-1991
		DE 69008507 D	01-06-1994
		DE 69008507 T	18-08-1994
		DK 437079 T	30-05-1994
		EP 0437079 A	17-07-1991
		ES 2053126 T	16-07-1994
		JP 6073475 A	15-03-1992
		ZA 9010217 A	30-10-1991

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